IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VENTANA MEDICAL SYSTEMS INC., Plaintiff, v. DAKOCYTOMATION CALIFORNIA INC., Defendant.	C. A. No. 04-1522-GMS

DECLARATION OF MICHAEL E. ZELIGER IN SUPPORT OF DEFENDANT'S MOTION FOR SUMMARY JUDGMENT OF NONINFRINGEMENT

I, Michael E. Zeliger, am *pro hac vice* counsel for Defendant DakoCytomation California Inc. ("Dako"), in this litigation. Under penalty of perjury, I declare the following to be true to the best of my knowledge, information, and belief:

1. Attached as Ex. A is a true and accurate copy of the Reply to Accompany an RCE dated April 16, 2004, submitted by the applicant during prosecution of the application which became the patent-in-suit.

2. Attached as Ex. B are true and accurate excerpts from the Artisan® Staining System User Guide.

3. Attached as Ex. C is a true and accurate copy of the Expert Report of Andre Sharon, Ph.D, dated January 31, 2006.

4. Attached as Ex. D are true and accurate excerpts from the Expert Report of Dr. Ari Glezer dated March 1, 2006.

Dated: March 15, 2006

By: */s/ Michael E. Zeliger*
Michael E. Zeliger

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on that on March 16, 2006, I electronically filed the foregoing DECLARATION OF MICHAEL E. ZELIGER IN SUPPORT OF DEFENDANT'S MOTION FOR SUMMARY JUDGMENT OF NONINFRINGEMENT with the Clerk of Court using CM/ECF which will send notification of such filing to the following:

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I HEREBY CERTIFY that on March 16, 2006, I mailed via Federal Express, the foregoing DECLARATION OF MICHAEL E. ZELIGER IN SUPPORT OF DEFENDANT'S MOTION FOR SUMMARY JUDGMENT OF NONINFRINGEMENT to the following non-registered participants:

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Exhibit A

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(Case No. 97,008-Y)

In re Application of:	)	
	)	
COPELAND, et. al	)	
	)	Group Art Unit: 1743
Serial No.: 10/137169	)	
	)	Examiner: Alexander Lyle
Filed: May 2, 2002	)	
	)	
For: Automated Biological Reaction Apparatus	)	

Commissioner for Patents
Box 1450
Alexandria, VA 22313-1450

REPLY TO ACCOMPANY AN RCE

This is a Reply to the October 22, 2003 Final Rejection for the above-captioned U.S. patent application. Please amend the above-identified application as follows:

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks begin on page 11 of this paper.

Listing Of Claims:

Claims 1-71 (cancelled)

72. (Currently amended) A biological reaction apparatus for dispensing a selected reagent to a slide containing a sample, said biological reaction apparatus comprising:

a reagent carousel having a plurality of reagent container supports thereon;

a homing and indexing device, operatively coupled to the reagent carousel, for identifying the position of each reagent container support with reference to a home position;

a motor engaging the reagent carousel and operatively coupled to said homing and indexing device, for rotating the reagent carousel and positioning a preselected reagent container support in a reagent supply zone, wherein said reagent supply zone is oriented so that reagent in a container in said preselected reagent container support is dispensable to a slide and wherein each of the reagent container supports is arranged to accommodate a reagent container such that it is positioned above a slide when in the reagent supply zone whereby the reagent is dispensable from a lower end of said container onto **athe** slide;

a sample carousel arranged beneath said reagent carousel for cooperation therewith, and having a plurality of slide supports with each slide support engaging a slide having a substantially planar support surface, said slide having a reagent agitation zone for adding and mixing reagents thereto located on the slide's upper surface; and

an air mixer comprising an air jet and an air supply means positioned adjacent to a said reagent agitation zone for mixing reagents, said air mixer directing a jet of air at the reagent agitation zone thereby inducing mixing in the reagent agitation zone.

73. (Previously presented) The biological reaction apparatus of claim 72, wherein said sample carousel may be arranged to allow said sample supports to be positioned in said reagent supply zone.

74. (Previously presented) The biological reaction apparatus of claim 72, wherein the reagent carousel is rotatably mounted on a reagent carousel support, and

wherein the homing and indexing device further comprises a proximity detector and an object detectable by the proximity detector when the proximity detector and said object are in close

proximity, one of said object and said proximity detector being mounted on the reagent carousel, and the other of the object and said proximity detector being mounted on the reagent carousel support in a position adjacent the path of the other.

75. (Previously presented) The biological reaction apparatus of claim 74, wherein said object is metallic and mounted on the reagent carousel, and

wherein the proximity detector is a metal proximity detector mounted on the reagent carousel support.

76. (Previously presented) The biological reaction apparatus of claim 75, wherein the reagent carousel is rotatably mounted on a reagent carousel support, the reagent carousel has a bar code zone, and

wherein the homing and indexing device further comprises a bar code reader mounted on the reagent carousel support in a position to read a bar code on a reagent container positioned in the bar code zone, whereby a bar code identifying the contents of a reagent container in the respective reagent container support can be read with reference to said home position by the bar code reader, and the reagent container containing said identified reagent can be automatically positioned in the reagent supply zone.

77. (Previously presented) The biological reaction apparatus of claim 76, further comprises a reagent delivery actuator positioned for engaging a reagent container positioned in the reagent delivery zone and initiating delivery of a predetermined volume of reagent from the reagent container to said slide.

78. (Previously presented) The biological reaction apparatus of claim 77, wherein the motor comprises a stepper motor having a rotational mode for rotating the reagent carousel and a braking mode resisting rotation of the reagent carousel.

79. (Previously presented) The biological reaction apparatus of claim 78, wherein the reagent carousel comprises a reagent support tray removably supported by a reagent tray support, the reagent support tray has indexing support feet on an underside thereof, the reagent tray support has

receptors for the indexing support feet in an upper surface thereof, whereby the reagent support tray can be removed from the reagent tray support for reloading or refrigerated storage and can be replaced on the reagent support tray in the same indexed position.

80. (Previously presented) The biological reaction apparatus of claim 79, wherein each sample support comprises a slide support plate having a distal end, a proximal end and a slide support surface, the distal end having raised terminal and lateral distal guide tabs with guide tab termini, the proximal end having first and second lateral guides with opposed surfaces for engaging the lateral edges of a slide, the distance between the slide support surface and the guide tab termini being less than a microscope slide thickness.

81. (Previously presented) The biological reaction apparatus of claim 80, wherein the slide support plate comprises a distal support section at the distal end and a proximal support section at the proximal end, the proximal support section comprising an inflexible support and a flexible arm with opposed lateral edges, and the distance between the slide engaging surfaces is less than a microscope slide width, whereby the slide engaging surfaces apply a positive pressure against the edges of a slide engaged therewith.

82. (Previously presented) The biological reaction apparatus of claim 81, wherein the distance between the slide engaging surfaces is from 20 to 24mm.

83. (Previously presented) The biological control apparatus of claim 82, further including a pivot support with a pivot axis, wherein the slide support plate is pivotally mounted on the pivot support for rotation around the pivot axis from a horizontal position to a slide draining position.

84. (Previously presented) The biological reaction apparatus of claim 83, wherein the pivot axis is defined by a pivot rod and a pivot rod receptor in sliding engagement therewith, one of the pivot rod and the pivot rod receptor being attached to or integral with the slide support and the other of the pivot rod and pivot rod receptor being attached to or integral with the pivot support.

85. (Previously presented) The biological reaction apparatus of claim 84, wherein the pivot axis is defined by two pivot rods and pivot rod receptors.

86. (Previously presented) The biological reaction apparatus of claim 82, wherein the slide support surface slopes downward from the proximal end to the distal end, the plane of the slide support surface forming an angle with the pivot axis of from 0.3 to 1 degree.

87. (Previously presented) The biological reaction apparatus of claim 83, wherein the slide support includes a lateral tilt cam surface for engagement by a tilt actuator.

88. (Previously presented) The biological reaction of claim 83, further comprising a rotational bias means for retaining the support surface in the substantially horizontal position when the tilt cam surface is not engaged by a tilt actuator.

89. (Previously presented) The biological reaction apparatus of claim 88 characterised in that the rotational bias means is a spring.

90. (Previously presented) The biological reaction apparatus of claim 83, wherein the pivot support has a pivot stop means positioned to abut a surface of the slide support for stopping pivotal rotation of the slide support when it has been pivoted to the slide draining position.

91. (Previously presented) The biological reaction apparatus of claim 73, wherein the homing and indexing device is operatively coupled to the slide support carousel, for identifying the position of each said slide support with reference to a home position; and

wherein the motor, engaging the slide support carousel and operatively coupled to said homing and indexing device, rotates the slide support carousel and positions a slide support in a reagent delivery zone.

92. (Previously presented) The biological reaction apparatus of claim 91, wherein the slide support carousel is rotatably mounted on a slide carousel support,

wherein the homing and indexing device comprises a proximity detector and an object detectable by the proximity detector when the proximity detector and said object are in close proximity, one of said object and said proximity detector being mounted on the slide support carousel, and the other of the object and said proximity detector being mounted on the slide carousel support in a position adjacent the path of the other.

93. (Previously presented) The biological reaction apparatus of claim 93, wherein said object is metallic and mounted on the slide support carousel and the proximity detector is a metal proximity detector mounted on the slide carousel support.

94. (Previously presented) The biological reaction apparatus of claim 91, wherein the slide support carousel is rotatably mounted on a slide carousel support,

wherein the slide support carousel has a bar code zone, and

wherein the homing and indexing device comprises a bar code zone, reader mounted on the slide carousel support in a position to read a bar code on a slide positioned in the bar code zone.

95. (Previously presented) The biological reaction apparatus of claim 91, characterised in that the motor comprises a stepper motor having a rotational mode for rotating the slide support carousel and a braking mode resisting rotation of the slide support carousel.

96. (Previously presented) The biological reaction apparatus of claim 95, further comprising a heating device for heating the samples.

97. (Previously presented) The biological reaction apparatus of claim 96, wherein the heating device comprises an air supply chamber communicating with the air distribution manifold, start-up and operational heating means positioned in the path of air passing from the air supply chamber to an air distribution manifold, the start-up heating means comprising means for heating air until the heating chamber has reached an operational temperature, and the operational heating means comprising means for heating air until the heating chamber has reached said operational temperature and for intermittently heating air thereafter to maintain the heating chamber at an operational temperature.

98. (Previously presented) The biological reaction apparatus of claim 97, wherein the heating device includes a fan positioned to force air into the air distribution manifold through the air supply chamber, said fan including air temperature responsive means for increasing the rotational speed of said fan when the air temperature entering the air distribution manifold falls below a desired operational temperature.

99. (Previously presented) The biological reaction apparatus of claim 96, further comprising a temperature sensing device positioned in the path of heated air entering an air distribution manifold for detecting the temperature of said heated air.

100. (Previously presented) The biological reaction apparatus of claim 99, wherein the temperature sensing device is a thermistor encased in a heat sensitivity reducing jacket.

101. (Previously presented) The biological reaction apparatus of claim 72, further comprising a rinse station, a rinse solution applicator positioned adjacent the rinse station, the rinse solution applicator comprising at least one nozzle positioned for directing a stream of rinse liquid onto a rinse solution impact zone of a sample support.

102. (Previously presented) The biological reaction apparatus of claim 72, further comprising an evaporation inhibiting liquid application station, evaporation inhibiting liquid applicator positioned adjacent to an application station, the evaporation inhibiting liquid applicator comprising at least one nozzle positioned for directing a stream of evaporation inhibiting liquid onto a preselected evaporation inhibiting liquid impact zone of a sample support.

103. (Previously presented) An automated biological reaction apparatus of claim 102, wherein the evaporation inhibiting liquid application station is in the reagent delivery zone.

104. (Previously presented) The biological reaction apparatus of claim 72, wherein the air mixer includes a vortex agitation mixer having a nozzle for directing air at the air agitation zone, said sample support being positionable in the air agitation zone.

105. (Previously presented) The biological reaction apparatus of claim 104, wherein the vortex agitation mixer comprises a nozzle for applying at least one gas stream to an off-center area of the surface of liquid on a slide in the air agitation zone.

106. (Previously presented) The biological reaction apparatus of claim 105, wherein the vortex agitation mixer comprises a first nozzle adjacent to a distal end of a slide support in the air agitation zone for directing a first gas stream to a first off-center area of the surface of the liquid on a slide in the air agitation zone, and a second nozzle adjacent to a proximal end of a slide support in the air agitation zone for directing a second gas stream to a second off-center area of the surface of the liquid on a slide in the air agitation zone, the first and second gas streams being in opposite directions and the first and second off-center areas being on opposite sides of the center of the surface of a liquid on a slide in the air agitation zone.

107. (Previously presented) The biological reaction apparatus of claim 72, further comprising apparatus for providing a sample rinse liquid within a selected temperature range, such apparatus comprising:

a container for receiving liquid;

temperature regulator, operatively mounted on said container, for maintaining liquid in the container within a selected temperature range; and

means, operatively coupled to said container, for delivering liquid at a temperature within said selected temperature range from the container to said sample.

108. (Previously presented) The biological reaction apparatus of claim 107, further comprising a safety thermostat connected to the heating device for terminating a flow of power to the heating device if the temperature of the container exceeds a predetermined safety limit.

109. (Previously presented) The biological reaction apparatus of claim 94, further comprising a bar code cleaner for cleaning bar codes on the slides.

110. (Previously presented) The biological reaction apparatus of claim 108, further comprising draining means for draining rinse solution from a sample.

111. (Previously presented) The biological reaction apparatus of claim 110, characterised in that the drain means comprises a jet drain for directing a jet of fluid across an upper surface of a slide.

112. (Previously presented) The biological reaction apparatus of claim 108, wherein the rinse solution applicator comprises a first rinsing means at a beginning of a rinse zone and a second rinsing means at an end of the rinse zone.

113. (Previously presented) The biological reaction apparatus of claim 112, wherein the first rinsing means includes at least one nozzle for depositing a layer of rinse liquid onto an upper surface of a slide positioned at the beginning of the rinse zone and the second rinsing means includes sweeping means for sweeping the layer of rinse liquid off of the slide when the slide reaches the end of the rinse zone.

114. (Previously presented) The biological reaction apparatus of claim 113, wherein the first rinsing means and the second rinsing means are spaced from one another so that a predetermined period of time transpires during the transport of the slide between the first and second rinsing means before the layer of rinse liquid is swept off of the slide.

115. (Previously presented) The biological reaction apparatus of claim 114, wherein the sweeping means of the second rinsing means comprises fluid pulsing means for forming pulsed streams of rinse liquid, alternately directed at one and then an other of longitudinal edges of the slides, to sweep the layer of rinse liquid off of the slide.

116 (New) A biological reaction apparatus for dispensing a selected reagent to a slide containing a sample, said biological reaction apparatus comprising:

a reagent carousel having a plurality of reagent container supports thereon;

a homing and indexing device, operatively coupled to the reagent carousel, for identifying the position of each reagent container support with reference to a home position;

a motor engaging the reagent carousel and operatively coupled to said homing and indexing device, for rotating the reagent carousel and positioning a preselected reagent container support in a reagent supply zone, wherein said reagent supply zone is oriented so that reagent in a container in said preselected reagent container support is dispensable to a slide sample and wherein each of the reagent container supports is arranged to accommodate a reagent container such that it is positioned above a slide sample when in the reagent supply zone whereby the reagent is dispensable from a lower end of said container onto the slide sample;

a carousel arranged beneath said reagent carousel for cooperation therewith, and having a plurality of slide supports with each slide support engaging a slide including a sample, said slide having a substantially planar support surface, said slide having a reagent agitation zone for adding and mixing reagents thereto located on the slide's upper surface; and

an air mixer comprising an air jet and an air supply means positioned adjacent to a said reagent agitation zone for mixing reagents, said air mixer directing a jet of air at the reagent agitation zone thereby inducing mixing in the reagent agitation zone.

REMARKS

Claims 72-116 are pending in the application. Claim 72 has been amended slightly to remedy a typographical error. The amendment to claim 72 does not narrow the claim in any manner. New claim 116 has been added to the application. New claim 116 is very similar to claim 72 except for the feature that the reagent dispenser dispenses reagent onto a sample located on a slide which is in turn located on a slide a slide carousel located below the reagent carousel. No new matter has been added to the application by way of these claim amendments.

The Examiners specification and claim objections and rejections are overcome or are traversed as set forth below.

I. TRAVERSE OF THE OBVIOUSNESS REJECTIONS

A. The Claimed Slides Are Not Obvious Equivalents Of Cuvettes

The examiner has issued two separate obviousness rejections of various claims. In both rejections, the examiner has noted that the prior art references relate to testing performed in cuvettes. However, it is the examiner's position for each ground for rejection that:

> With respect to the use of a slide it would have been obvious to one or ordinary skill in the art to have replaced the cuvette . . . with a slide carousel, since microscope slides and cuvettes are know equivalents for biological analysis [in] the analyzer art, see (Kamentsky et al. USP 5,107,422, col. 4, lines 22-25.

The examiner's reliance on Kamentsky et al. for teaching that slides are equivalent to cuvettes is misplaced. Moreover, one of ordinary skill in the art would understand that slide and cuvettes are not interchangeable, they each have their own unique uses and are not interchangeable.

The Kamentsky et al. reference relied upon by the Examiner does not disclose that slides in cuvettes are interchangeable for all purposes. However, the Examiner has taken that position. Kamentsky et al. is directed to methods and apparatuses for measuring multiple optical properties of biological specimens such as populations of blood cells and so forth. Accordingly, Kamentsky et al. teaches that the biological specimens can be applied to slides or cuvettes. However, not all biological testing is performed on cells. The apparatuses of the present invention are generally but not exclusively useful for testing solid biological specimens. In contrast, cuvettes are most useful in testing aqueous biological samples or solutions. Clearly, therefore slides and cuvettes are not universally interchangeable. For example, it would be impossible to use a cuvette to test a solid biological specimen where the goal of the

testing is to review the specimen under a microscope or by some other means to evaluate the uptake of a particular stain on the biological sample. For at least this reason, the Examiner's conclusion that it would be obvious to replace a cuvette with a slide is incorrect. The applicants respectfully request that the Examiner withdraw his obviousness rejection of all claims because the Examiner has not shown that it would have been obvious to one or ordinary skill in the art to modify the apparatus of the prior art for use in testing biological samples held on slides, instead of cuvettes.

B. Traverse Of The Hulette and Kelln et al. Obviousness Rejection

The Examiner rejected claims 72-82, 91-96 and 101-106 for being obvious of Hulette (WO 85/03571) in view of Kelln et al. et al. (USP 4,764,342). It is the Examiner's position that Hulette in combination with Kellen et al. renders obvious the claims recited above.

The combination of Hulette with Kelln et al. et al. does not render claims 72-82, 91-96 and 101-106 obvious for at least the following reasons:

- Neither reference discloses or suggests a "sample carousel arranged beneath said reagent carousel" wherein reagent is dispensed onto a slide positioned below the reagent carousel of claims 72 et al.
- Neither reference discloses or suggests a "slide having a reagent agitation zone" of claims 74 et al.
- Neither reference discloses the reagent support tray feet feature of claims 79-82.
- Neither reference discloses or suggests the slide support features of claims 80-82.
- Neither reference discloses or suggests that the samples undergoing testing are associated with a carousel or with a carousel that includes a homing and indexing device of claims 91-96 et al.
- Neither reference discloses the container for sample analysis that includes a bar code of claims 94-96 et al.
- Neither reference discloses the rinse station of claims 101-103.
- Neither reference discloses an evaporation inhibiting liquid application station of claim 102-103.

- Neither reference discloses the feature of using two nozzles to agitate a liquid on a slide of claim 106.

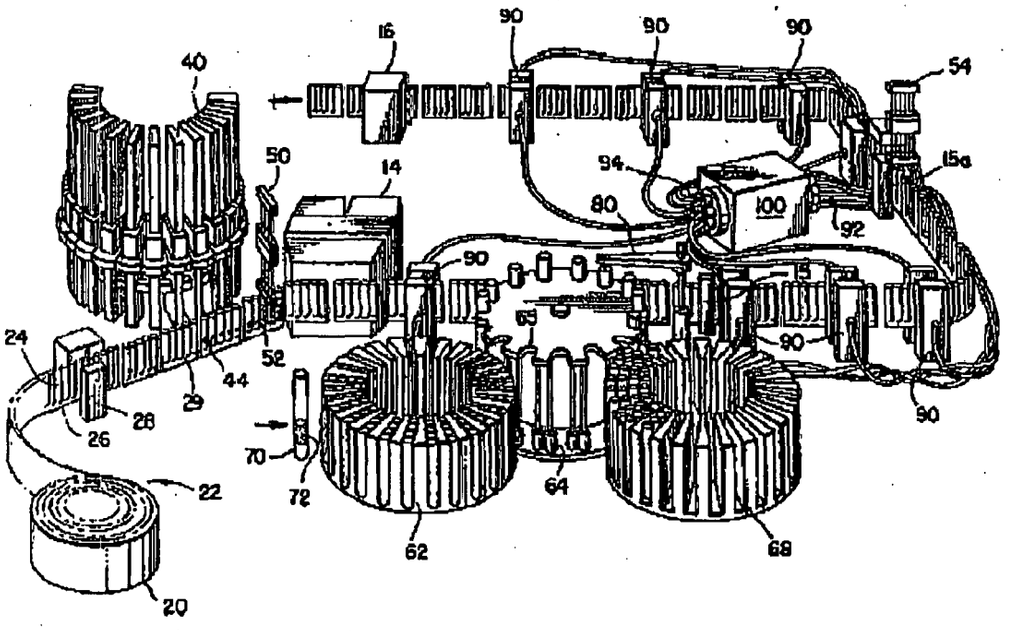
Each of the grounds recited above and explained in more detail below demonstrates that one or more of the rejected claims are patentable over the prior art of record.

1. The prior art does not disclose or suggest the "sample carousel arranged beneath said reagent carousel" wherein reagent is dispensed onto a slide positioned below the reagent carousel of claims 72 et al.

Pending claims 72 et al. are directed to an apparatus for "dispensing a selected reagent to a slide containing a sample ..." Thus, the Applicants use the term sample and slide similarly to refer to a slide that includes a biological sample that will undergo testing in the claimed biological reaction apparatus. (See, *e.g.*, page 4, lines 4-12 of the specification).

In one aspect, the claimed invention includes (1) a reagent carousel having a plurality of reagent containers; and (2) a sample carousel arranged beneath said reagent carousel for cooperation therewith wherein the reagent is dispensable from a lower end of said container onto a slide. (See *e.g.*, claim 72). Neither Hulette nor Kelln et al. disclose an apparatus that includes a reagent carousel located above a sample carousel wherein reagent is applied to sample containing slides held in place on the sample carousel as set forth in claims 72 et al. Figure 2 of Hulette which depicts an automated chemical analyzer described in the patent is reproduced below.

FIG. 2.



In Figure 2:

The cuvettes 24 are supplied from a supply reel 20 as a continuous cuvette belt 22 and are indexed through the analyzer by tractor conveyer 30 which engages a row of index holes in the cuvette belt. The cuvettes are indexed in turn past the following stations: a belt cutter 28 ... a tableted reagent dispenser 40; a diluent and liquid reagent dispenser 50; an ultrasonic mixing horn 14; a sample dispenser 80 for dispensing biological samples filtered by transferred carousel 64 ... (page 12, lines 14-24).

# # #

A sample loading and transfer carousel assembly 60 is located downstream of the reagent and diluent dispensers. This carousel assembly comprises a loading carousel 62 in which patient sample 70 are randomly loaded; a transfer carousel 64 which accepts the patient samples from loading carousel 62 .... (page 16, lines 3-80).

# # #

Sampler 80 for dispensing samples into the cuvette 24 at point "SD" is located adjacent to transfer carousel 54. This sampler is designed to aspirate about 2 to 20 microliters of patient sample 70 from its container and the transfer carousel and dispense

it into a cuvette 24 during the four second dwell period while the cuvette is aligned with the sampler. (page 16, lines 26-33).

From Hulette Figure 2 above and accompanying description, it is clear that cuvettes 24 in which samples are tested are not located on a carousel. Moreover, the Hulette carousels (e.g. number 68) are not used as a receptacles for containers including testing solutions. Instead the carousels hold bulk liquid sample containers from which a portion of the liquid sample is dispensed into an cuvette for testing. The testing cuvette is located adjacent to and not beneath the reagent carousel as is required by all pending application claims.

The Kelln et al. et al. reference does not supply this missing teaching. In Kelln et al., reagents and bulk samples are located on carousels. However, both the reagents and the bulk samples are transferred by pipettes into cuvettes 106 held in sample analysis carousels 102 that are adjacent to and not below the reagent carousel. This procedure is set forth in the specification with reference to Figure 9 which is reproduced below.

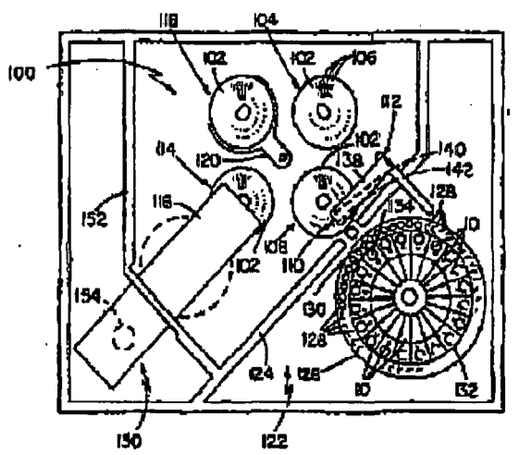


FIG. 9

In system operation to transfer sample and reagent from container 10 and 126 to cuvette 106 of a rotor 102 at loading station 108, transfer arm 138 moves the pipes at 140, 142 into the alignment with the selected reagent and sample containers so when positioned at the sample in reagent loading stations by their respective driver .... the transport arm is lowered to insert the tips of pipette 140 through membrane 32 are capped web 46 into reagent into the container 10 at the reagent station while pipette 42 passes into channel 60 and the metering syringe draws a specified volume of a reagent into pipette 140 the transfer arm 138 has been lifted and moved to position pipette 140 at the sample station while the reagent table 132 is indexed to position a second container 110 at reagent position 134; the two pipettes are lowered concurrently into a sample cup 128 and the different reagent container 10 and the volume of sample and second reagent specified

> by the system controller are drawn up into the pipettes. The transfer arm 138 is then lifted and move laterally to the loading station 110, the pipettes lowered through the ports of the cuvette 106 of the loading station 110 and the pipette of volume of sample and reagents are dispensed into their respective chambers of that cuvette. (col. 6, line 58 to col. 7, line line17).

This description of the Kelln et al. et al. apparatus demonstrates that testing cuvettes are located in a cuvette rotor 102 that is adjacent to reagent table 132 and not beneath the reagent carousel as is required by every application claim.

As established above, neither the Kelln et al. et al. apparatus, nor the Hulette apparatus, include "a sample carousel arranged beneath said reagent carousel" positioned in relation to the reagent carousel such that "the reagent is dispensable for a lower end of said container onto a slide". (See *e.g.*, claim 72). For at least this reason, all pending application claims are not obvious over Hulette in combination with Kelln et al. et al.

2. The prior art does not disclose or suggest a "slide having a reagent agitation zone" of claims 74 et al.

The prior art of record does not disclose a "slide having a reagent agitation zone" as set forth in claims 74 et al. As a result, all claims that include a slide having a reagent agitation zone are believed to be non-obvious and patentable over the prior art of record.

Both Hulette and Kelln et al. are directed to apparatuses and methods that perform analyses in cuvettes. It is the Examiner's position that it would have been obvious to modify the claimed invention to include the cuvette air agitation apparatus of Hulette et al. The Applicants respectfully traverse the Examiner's conclusion.

Hulette discloses using an air jet to agitate the contents of a cuvette. A cuvette is a container with an open end that is partially filled with a liquid. Air is supplied directed into the container to agitate the liquid contents of the cuvette. Importantly, the cuvettes of Hulette et al. are not completely full. This means that there is little or no concern about the air jet expelling fluid form the container.

It would not be obvious to use the air jet of Hulette to agitate liquids located on the slide because agitating liquids on slides pose difficult and unexpected agitation problems. Slides do not have a receptacle to hold liquids. Therefore, liquids remain on a slide primarily by virtue of (1) the association of the liquid with a solid biological sample; and (2) by its surface tension. One of ordinary skill in the art at the time of the Applicant's invention would understand, based upon the cited references, that applying

air to a mix a liquid located on the slide would not be an obvious task since an air stream could likely direct some or all of the liquid off of the slide.

It appears in this case that the Examiner's rejection of the application claims on the grounds that it would have been obvious to apply the cuvette air mixing apparatus of Hulette to the claimed invention is based upon in hindsight analysis of the prior art. There is absolutely no disclosure or suggestion in the prior art cited above that would lead one of ordinary skill in the art to understand that liquids located on slides could be mixed in an agitation zone with an air stream.

3. The prior art does not disclose or suggest the reagent support tray feet feature of claims 79-82

Claim 79 includes a feature whereby the reagent carousel is removeably associated with a reagent tray support such that the reagent support tray can be removed and replaced on reagent tray support in the same index position because of indexing support feet located on the underside of the reagent support tray. Neither of the prior art references cited by the Examiner includes this feature. Nor has the Examiner identified any particular teaching in either prior art reference that discloses a teaching. For at least this reason, the Examiner's rejection of claims 79-82 for obviousness should be withdrawn.

4. The prior art does not disclose or suggest the slide support features of claims 80-82

Claims 80-82 recite specific slide support features. The specified sample supports are designed to accept slides including samples that will undergo testing.

The Examiner has admitted that neither Hulette nor Kelln et al. disclose apparatuses that perform samples on slides. Therefore, it is believed that neither of the references discloses the slide support features of claims 80-82. As a result, the Examiner has not made out a *prima facie* case of obviousness with respect to claims 80-82 and the Examiner's obviousness rejection of these claims should be withdrawn.

5. The prior art does not disclose or suggest slide/sample carousels that includes a homing and indexing device of claims 91-96 et al.

Claim 91 is directed to an apparatus whereby the slide support carousel includes a homing and indexing device. Neither Hulette nor Kelln et al. et al. disclose or suggest a carousel including such a homing and indexing device.

As set forth in Section 1 above, neither Hulette nor Kelln et al. are directed to apparatuses whereby a slide support or sample carousel is located below a reagent carousel. In Hulette, the reagent is applied to a sample in a linear array of cuvettes. The samples undergoing testing are never held in a carousel. In Kelln et al. et al., the sample and reagent are applied to cuvettes 106 located in rotors 102. There is no disclosure or suggestion in Kelln et al. that the carousels that include samples also include some type of homing device. For at least this reason, claims 91-96 are not obvious over Hulette in combination with Kelln et al..

6. The prior art does not disclose or suggest sample analysis slides that include bar codes of claims 94-96 et al.

Claims 94-96 include the feature whereby the slide support carousel has bar code zone and a corresponding bar code reader. Neither Hulette nor Kelln et al. disclose an apparatus including a bar code zone associated with a holder for a sample that is undergoing testing. Hulette does disclose associating a bar code with a liquid patient sample. However, a portion of that sample is subsequently removed from the sample container and placed into a cuvette along with a reagent for testing. Hulette nor Kelln et al. disclose or suggest associating a bar code and a bar coder reader with a carousel that holds samples undergoing testing. For at least this reason, claims 94-96 are believed to be patentable over the prior art of record.

7. The prior art does not disclose or suggest the rinse stations of claim 101

Claim 101 includes a rinse station feature. Neither Hulette nor Kelln et al. disclose an apparatus including a rinse station. For at least this reason, claim 101 is believed to be patentable over the prior art of record.

8. The prior art does not disclose or suggest the evaporation inhibiting liquid application stations of claims 102-103

Claims 102-103 include an evaporation inhibiting liquid application station feature. Once again, neither Hulette nor Kelln et al. disclose or suggest the use of an evaporation inhibiting liquid application station in conjunction with a reagent handling apparatus. For at least this reason, claims 102-103 are believed to be patentable over the prior art of record.

9. The prior art does not disclose or suggest the feature of using two nozzles to agitate a liquid on a slide of claim 106

Claim 106 includes the feature of using a first nozzle and a second nozzle to direct two separate gas streams to a liquid on a slide in order to agitate the liquid. The Examiner has cited Kelln et al. for disclosing using a nozzle and an air jet to agitate a liquid in a cuvette. However, there is no disclosure or suggestion in Hulette that two separate air streams can be used simultaneously to agitate a liquid. The specification states that using two air streams to agitate a liquid on a slide provides the advantage of directing the liquid on the slide in two different directions. This advantage is not obvious and for at least this reason, claim 106 is believed to be patentable over the prior art of record.

B. Traverse Of The Sakurada, Rokugawa and Gibbs et al. Obviousness Rejection

The Examiner also rejected claims 72-79 and 102-106 for being obvious over Sakurada (USP 4,346,056) in view of Rokugawa (USP 4,844,868) and Gibbs et al. (USP 3,854,703).

This combination of references does not disclose or suggest the claimed invention for at least each of the following reasons:

- No cited reference discloses or suggests a "sample carousel arranged beneath said reagent carousel" wherein reagent is dispensed onto a slide positioned below the reagent carousel of claims 72 et al.
- No cited reference discloses the reagent support tray feet feature of claim 79.
- Neither reference discloses an evaporation inhibiting liquid application station of claim 102-103.

Each of the grounds recited above and explained in more detail below demonstrates that one or more of the rejected claims are patentable over the prior art of record.

1. **The prior art does not disclose or suggest a "sample carousel arranged beneath said reagent carousel" wherein reagent is dispensed onto a slide positioned below the reagent carousel of claims 72 et al.**

As set forth in Section A(1) above, the invention of claim 72 et al. includes a sample carousel arranged beneath a reagent carousel or when the reagent is dispensed onto a slides position below the reagent carousel. Neither Sakurda, Rokugawa or Gibbs disclose such an arrangement. In Sakurda, the sample carousel is adjacent to the reagent carousel. In Rokugawa, the reagents are located in the carousel while samples are located in trapezoidal containers adjacent to the reagent carousel. Finally in Gibbs, samples are located on a moving strip.

Locating the carousel including samples containing slides below the reagent carousel is an important feature of the claimed invention because it allows the reagent to be applied directly to the samples on the slides. All application claims, therefore are believed to be patentable over the three references cited above because they do not disclose or suggest this feature of the claimed invention.

2. **The prior art does not disclose or suggest the support tray feet features of claim 79**

Claim 79 includes a feature whereby the reagent carousel is removably associated with a reagent tray support such that the reagent support tray can be removed and replaced on reagent tray support in the same index position because of indexing support feet located on the underside of the reagent support tray. None of the three prior art references cited by the Examiner above includes this feature. Nor has the Examiner identified any particular teaching in the prior art references that disclose or suggest the tray support feet feature of claims 79. For at least this reason, the Examiner's rejection of claim 79 for obviousness should be withdrawn.

3. **The prior art does not disclose or suggest evaporation inhibiting liquid application stations of claim 102-103**

Claims 102-103 include an evaporation inhibiting liquid application station feature. None of the three prior art references cited by the Examiner above disclose or suggest the use of an evaporation inhibiting liquid application station in conjunction with reagent handling apparatus. For at least this reason, claims 102-103 are believed to be patentable over the three prior art references cited by the Examiner in this rejection.

II. New Claim 116 Is Patentable

Claim 116 has been added to the application and includes the limitation whereby a reagent in a reagent container is applied to a sample located on the slide which in turn is positioned immediately below the reagent container. New claim 116 is believed to be patentable over the prior art of record because none of the references disclose or suggest such a reagent application orientation.

III. Patentable Subject Matter

The Applicants acknowledge that the Examiner has allowed application claims 83-90, 97-100, 107-108 and 110-115.

Conclusion

Pending application claims 72-116 are believed to be patentable for the reasons indicated above. Favorable reconsideration and allowance of all pending application claims is, therefore, courteously solicited.

Respectfully submitted,

McDonnell Boehnen Hulbert & Berghoff LLP

By: _____

A. Blair Hughes
Reg. No. 32,901
312-913-2123

Date: April 16, 2004

Exhibit B

DakoCytomation

Artisan® Staining System User Guide

Document Number 0000788

Revision A

November 2004

The Artisan® Staining System and its associated components and reagents are covered under the following U.S. patents:

5,073,504	4,847,208	5,316,452	5,645,114	5,947,167
6,092,695	6,096,271	6,180,061B1	6,183,693B1	6,465,207
6,541,261				

Additional U.S. and foreign patents are pending.

User Resources

For the latest information on DakoCytomation products and services, please visit the DakoCytomation website at:
http://www.dakocytomation.com

Installation Procedure

DakoCytomation employees will perform the initial installation and setup of all new Artisan instruments.

Relocation Procedure

Contact DakoCytomation's Technical Service Group before relocating your Artisan Staining System.

Scope

This guide contains basic information on the use and operation of the Artisan® Staining System and assumes you have received basic training on the instrument. Please contact our Technical Service Group or refer to the Artisan® Staining System User Guide for information not provided in this user guide. This guide does **not** provide instructions for the installation or upgrade of software or hardware.

Disclaimers

This user guide is not a substitute for the detailed operator training provided by DakoCytomation, Inc., or for other advanced instruction. DakoCytomation Technical Service Group should be contacted immediately for assistance in the event of any instrument malfunction. Installation of hardware or software on your Artisan® Staining System should be performed only by a certified DakoCytomation Field Service Representative.

Trademarks

Manufacturer

DakoCytomation, Inc
6392 Via Real
Carpinteria, CA 93013 USA
www.dakocytomation.us

Corporate Headquarters:
DakoCytomation Denmark A/S
Produktionsvej 42
DK-2600 Glostrup Denmark
www.dakocytomation.com

Customer Support

Contact your local representative.

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SECTION 4

SYSTEM OVERVIEW

The Artisan® Staining System is a new generation of staining automation, providing you with the flexibility of manual staining coupled with the precision and consistency of automation. The Artisan has the ability to simultaneously perform both special stains and immunohistochemical (IHC) stains in the same run. The reagent carousel with up to 50 reagent packs and the slide carousel with up to 48 slides independently rotate to the position specified by the preprogrammed or customized staining protocols. Slide clips create a reaction chamber which allows the addition of any reagent to any of the 48 slide positions, providing users with the flexibility to load any special stain or IHC procedure in any slide position.

Bar codes on the Artisan ready-to-use reagent packs enable the system to manage reagent requirements and usage automatically. If a required reagent is missing, expired, or the quantity is insufficient for the number of slides loaded, the system will prompt you to add reagent packs. The Artisan can also accept multiple packs of the same kit on the instrument. This unique feature ensures cost effective use of reagents, lowering total operational costs.

After a staining run is initiated, slides are automatically sorted to minimize total run time and to meet procedure timing criteria. Each slide rotates to the dispensing station, where the appropriate reagent pack positions itself above the slide. A dispenser assembly at the base of the reagent pack releases a measured volume of reagent directly onto the slide. A gentle, reciprocating air stream mixes and evenly distributes the reagents over the surface of the slide. During the incubation cycle, each slide can be independently heated up to 65°C.

Following each staining sequence and wash cycle, fluids are aspirated and segregated to one of four waste receptacles. Each slide sequences through similar steps, as specified by the procedure selected for it.

At the completion of a staining run, the system provides users with a wide range of reports.

Artisan Staining System Components

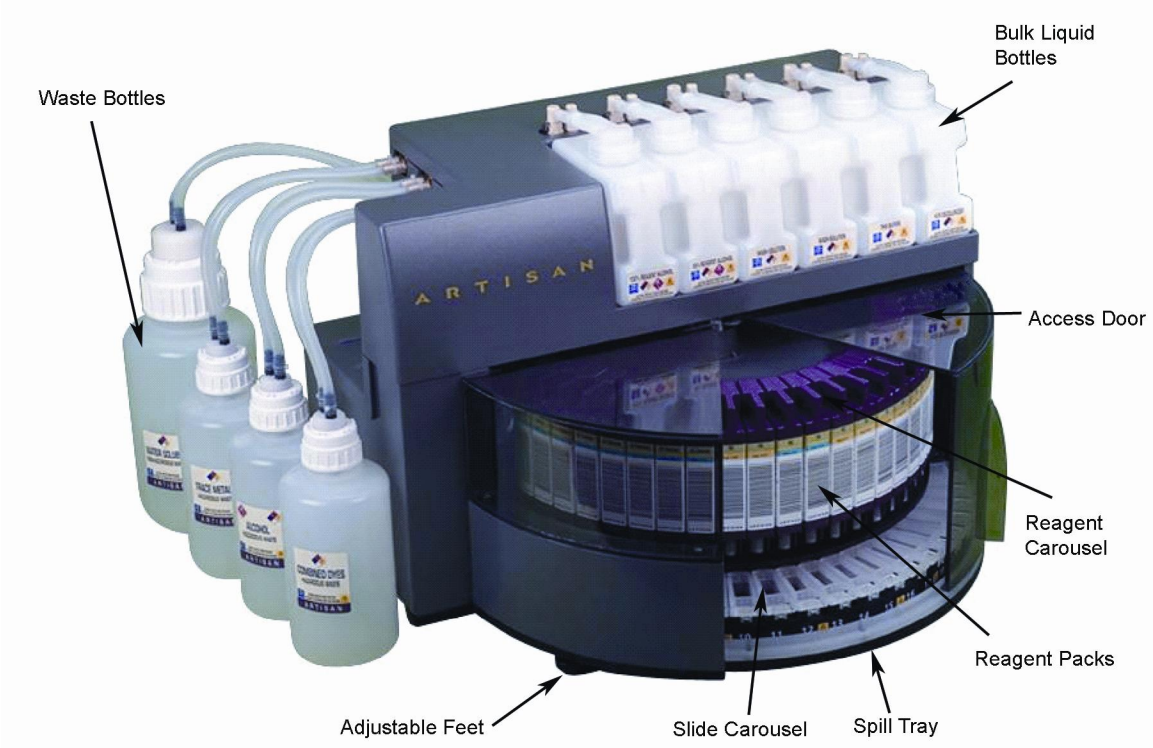


Exhibit C

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VENTANA MEDICAL SYSTEMS, INC., Plaintiff, v. DAKOCYTOMATION CALIFORNIA INC., Defendant.	C.A. No. 04-1522-GMS

EXPERT REPORT OF ANDRE SHARON, Ph.D.

1. I am a Professor of Manufacturing Engineering at Boston University and the Executive Director of the Fraunhofer Center for Manufacturing Innovation. Prior to joining the Fraunhofer Center for Manufacturing Innovation and Boston University, I co-founded and served as the Executive Officer of the Massachusetts Institute of Technology Manufacturing Institute. I also served as the Associate Director of the Massachusetts Institute of Technology Laboratory for Manufacturing and Productivity.

2. I received my Bachelor of Science degree from the Polytechnic Institute of New York, and my Master of Science and Doctor of Philosophy degrees from the Massachusetts Institute of Technology. A copy of my resume is attached as Exhibit A, and a list of my publications is attached as Exhibit B.

3. I have twenty years of academic and industrial experience developing and deploying state-of-the-art automation to industry, ranging from sub-micron, high-precision machinery for optoelectronics, biotechnology, and semiconductor manufacturing to high-speed assembly of consumer products. I am the Editor-in-Chief of the International Journal, Robotics and Computer Integrated Manufacturing. I am a named inventor on six issued United States patents.

4. I have been retained by the firm of Wilson Sonsini Goodrich & Rosati as a consultant in connection with the above-captioned lawsuit. For my work on this matter, I am being compensated at my consulting rate of $250 per hour for non-testifying time, and $350 per hour for deposition and courtroom appearances. In the preceding four years, I have testified as an expert by deposition in *Vision BioSystems (Trading) USA, Inc. v. Ventana Medical Systems, Inc.*, Case No. 03-CV-10391-GAO (D. Mass.) and *Ventana Medical Systems, Inc. v. BioGenex Laboratories, Inc.*, Case No. No. CV-03-92-TUC-RCC (D. Ariz.).

5. If called as an expert witness in this matter, I anticipate that my testimony may concern the matters addressed below. My anticipated testimony may be affected by the production of additional information and/or positions defendant takes on the topics set forth in this report. I have been informed that defendant may communicate at least some of those positions to plaintiff some time after this report is prepared, such as in the form of deposition testimony to be given by its experts. After I have an opportunity to review those materials, I may amend or supplement this report.

6. In connection with formulating the opinions set forth in this report, I have reviewed at least the material listed in the attached Exhibit C.

7. I have been asked to compare claims 1, 2, 3, and 45 of U.S. Patent No. 6,827,901 ("the '901 patent") with the Artisan Staining System sold by DakoCytomation California, Inc. ("the Artisan").

8. Claims 1, 2, 3, and 45 of the '901 patent read as follows:

> 1. A biological reaction apparatus for dispensing a selected reagent to a slide containing a sample, said biological reaction apparatus comprising:
>
> [a] a reagent carousel having a plurality of reagent container supports thereon;
>
> [b] a homing and indexing device, operatively coupled to the reagent carousel, for identifying the position of each reagent container support with reference to a home position;
>
> [c] a motor engaging the reagent carousel and operatively coupled to said homing and indexing device, for rotating the reagent carousel and

positioning a preselected reagent container support in a reagent supply zone, wherein said reagent supply zone is oriented so that reagent in a container in said preselected reagent container support is dispensable to a slide and wherein each of the reagent container supports is arranged to accommodate a reagent container such that it is positioned above a slide when in the reagent supply zone whereby the reagent is dispensable from a lower end of said container onto the slide;

[d] a sample carousel arranged beneath said reagent carousel for cooperation therewith, and having a plurality of slide supports with each slide support engaging a slide having a substantially planar support surface, said slide having a reagent agitation zone for adding and mixing reagents thereto located on the slide's upper surface; and

[e] an air mixer comprising an air jet and an air supply means positioned adjacent to a said reagent agitation zone for mixing reagents, said air mixer directing a jet of air at the reagent agitation zone thereby inducing mixing in the reagent agitation zone.

2. The biological reaction apparatus of claim 1, wherein said sample carousel may be arranged to allow said sample supports to be positioned in said reagent supply zone.

3. The biological reaction apparatus of claim 1, wherein the reagent carousel is rotatably mounted on a reagent carousel support, and

wherein the homing and indexing device further comprises a proximity detector and an object detectable by the proximity detector when the proximity detector and said object are in close proximity, one of said object and said proximity detector being mounted on the reagent carousel, and the other of the object and said proximity detector being mounted on the reagent carousel support in a position adjacent the path of the other.

45. A biological reaction apparatus for dispensing a selected reagent to a slide containing a sample, said biological reaction apparatus comprising:

[a] a reagent carousel having a plurality of reagent container supports thereon;

[b] a homing and indexing device, operatively coupled to the reagent carousel, for identifying the position of each reagent container support with reference to a home position;

[c] a motor engaging the reagent carousel and operatively coupled to said homing and indexing device, for rotating the reagent carousel and positioning a preselected reagent container support in a reagent supply zone, wherein said reagent supply zone is oriented so that reagent in a container in said preselected reagent container support is dispensable to a slide sample and wherein each of the reagent container supports is arranged to accommodate a reagent container such that it is positioned above a slide sample when in the reagent supply zone whereby the reagent is dispensable from a lower end of said container onto the slide sample;

[d] a carousel arranged beneath said reagent carousel for cooperation therewith, and having a plurality of slide supports with each slide support engaging a slide including a sample, said slide having a substantially planar support surface, said slide having a reagent agitation zone for adding and mixing reagents thereto located on the slide's upper surface; and

[e] an air mixer comprising an air jet and an air supply means positioned adjacent to said reagent agitation zone for mixing reagents, said air mixer directing a jet of air at the reagent agitation zone thereby inducing mixing in the reagent agitation zone.

I have identified the elements of claims 1 and 45 by bracketed letters for ease of reference.

9. I understand that the Court has provided the following definitions of claim language:

"**reagent agitation zone**" means "an area on the slide's upper surface where reagents are added and mixed."

"**air mixer**" means "the device, including the air jet and the air supply means, that is positioned adjacent to the reagent agitation zone for mixing reagents."

"**air jet**" means "a stream of air."

"**air supply means**" means "a device for supplying air, comprising the nozzle."

"**adjacent**" means "next to, but not above or beneath."

10. As explained below, I conclude that the Artisan includes all the elements of claims 1, 2, 3 and 45. My analysis cites various pertinent evidence, but other evidence that I reviewed is also relevant to these issues. Additionally, my inspection of the Artisan on January 6, 2006, confirms the operation of these systems, as described below. I may use photographs and videotapes from the inspection to further support my opinions.

Claim 1

11. The preamble of claim 1 calls for a "biological reaction apparatus for dispensing a selected reagent to a slide containing a sample." The Artisan is such an

apparatus. It is DakoCytomation's "new generation of staining automation, providing you with the flexibility of manual staining coupled with the precision and consistency of automation." Artisan Staining System User Guide ("User Guide"), Rev. A (June 2005) p. 13. The User Guide describes the ability of the Artisan to dispense reagents to a slide containing a sample. The "dispenser assembly at the base of the reagent pack releases a measured volume of reagent directly onto the slide." User Guide p. 13. This is consistent with the preamble.

12. Element [a] of claim 1 calls for "a reagent carousel having a plurality of reagent container supports thereon." Mr. Scott Leon, DakoCytomation's Director of Operations, confirmed that "The Artisan has a reagent carousel." Leon Depo. p. 39:12-15. The reagent carousel can hold "up to 50 reagent packs." User Guide p. 13. Mr. Leon confirmed that on the reagent carousel there is one slot for each of the 50 reagent pack positions. *See* Leon Depo. p. 54:7-10 ("Q. (By Mr. Reed) Right. The question is, on the reagent carousel there is a slot for each of the 50 reagent pack positions, correct? A. Correct."). The User Guide instructs users as follows: "Holding the reagent pack in one hand, slide the mounting guide on the back of the reagent pack into the slots on the reagent carousel until the pack is completely seated." User Guide p. 77. Once seated, the reagent pack is supported such that it is constrained at least circumferentially and radially through the interaction of the reagent pack mounting guide and the slots described above. The slots are the plurality of reagent container supports called for in element [a] of claim 1. The testimony of Mr. Leon and the description of the Artisan given in DakoCytomation documentation were confirmed by my own observations of the Artisan.

13. Element [b] of claim 1 calls for "a homing and indexing device, operatively coupled to the reagent carousel, for identifying the position of each reagent container support with reference to a home position." The Artisan reagent carousel positioning system includes a "reagent carousel motor assembly and the reagent

carousel home sensor. The home sensor detects the carousel home position, allowing the carousel to be positioned precisely by the motor assembly." Artisan Staining System Service Manual ("Service Manual") Rev. A (Nov. 2004) p. 14. Furthermore, "All reagent positions are based off the home position." Artisan: Mechanical System Overview ("Overview") by Jim Russo (April 2004) p. DC 042542. The home sensor together with the encoder of the reagent carousel motor and associated control circuitry and algorithms constitute the "homing and indexing device" described in the claim. *See* Overview p. DC 042542 ("The reagent positioning system has a servo motor and an encoder for monitoring the carousel position relative to the home position."). This allows the Artisan to identify each reagent container position with reference to the home position, making it operatively coupled to the reagent carousel.

14. Element [c] of claim 1 calls for "a motor engaging the reagent carousel and operatively coupled to said homing and indexing device, for rotating the reagent carousel and positioning a preselected reagent container support in a reagent supply zone, wherein said reagent supply zone is oriented so that reagent in a container in said preselected reagent container support is dispensable to a slide and wherein each of the reagent container supports is arranged to accommodate a reagent container such that it is positioned above a slide when in the reagent supply zone whereby the reagent is dispensable from a lower end of said container onto the slide." The Artisan Service Manual depicts a reagent carousel motor in Figure 8-15, shown below:

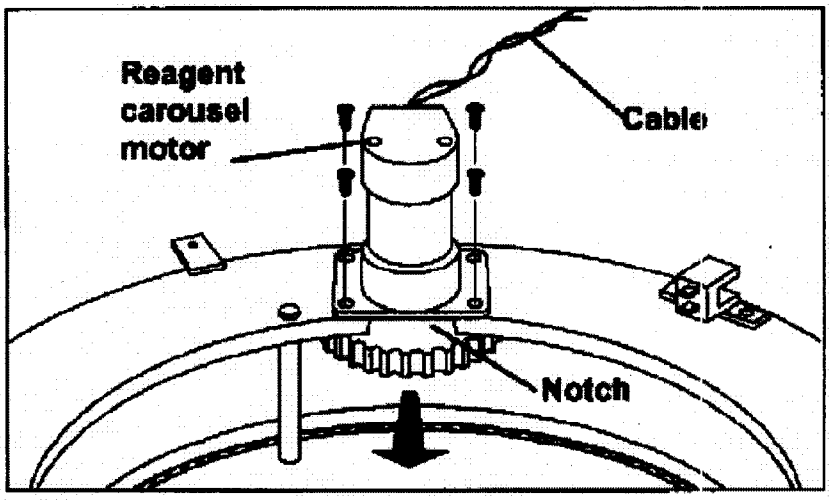
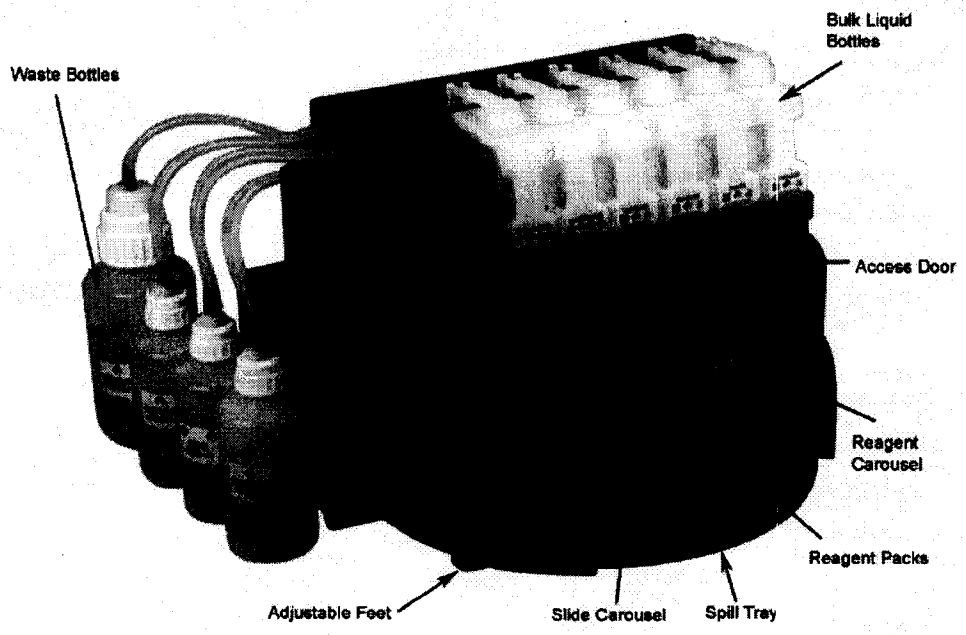


Figure 8-15. Removal of reagent carousel motor assembly

Also shown in the figure above, but not labeled, are the reagent carousel home sensor (on the right side of the motor) and the reagent carousel home sensor flag (on the left side of the motor). The Artisan reagent carousel positioning system includes a "reagent carousel motor assembly and the reagent carousel home sensor. The home sensor detects the carousel home position, allowing the carousel to be positioned precisely by the motor assembly." Service Manual p. 14. The motor is thereby operatively coupled to the homing and indexing device (described in paragraph 13 above) as stated in the claim. The reagent carousel positioning system of the Artisan "positions each slide under a reagent dispensing station for application of measured amounts of reagents. The reagent carousel, located above the slide carousel and controlled separately, positions the appropriate reagent pack at the dispensing station for application of that reagent to the slide on the slide carousel below." Service Manual p. 12. Mr. Leon confirmed that the reagent is dispensable from the lower end of the reagent pack as called for in element [c]. Leon Depo. p. 50:25-51:2 (Q. And that dispenser mechanism dispenses the reagent out the bottom of the reagent pack, correct? A. That's correct."). All of this was confirmed by my own observation of the Artisan.

15. Element [d] of claim 1 calls for "a sample carousel arranged beneath said reagent carousel for cooperation therewith, and having a plurality of slide supports with each slide support engaging a slide having a substantially planar support surface, said slide having a reagent agitation zone for adding and mixing reagents thereto located on the slide's upper surface." The Artisan includes a slide carousel that "is under or beneath the reagent carousel." Leon Depo. p. 51:25-52:5. The slide carousel beneath the reagent carousel is illustrated in the photograph on page 14 of the User Guide:



The slide carousel includes flat heater plates on which the slides rest. *See* Leon Depo. p. 55:19-56:3 ("A. The slides don't rest on the heaters. They rest on the heater plate, then underneath the heater plate are the heaters. Q. So the heater plate is the metal portion you can see from above? A. And that's flat. Q. That's flat, just like the slide? A. It's flat – where the slide rests it's flat."). The slides used with the Artisan are flat, common microscope slides. *See* Leon Depo. p. 55:16-18 ("Q. The slides are flat slides, common microscope slides, correct? A. Correct."). This is consistent with my own

observation in which I saw a slide carousel with 48 individual heater plates, each of which would support a microscope slide. On each slide, there is a reagent agitation zone, which I was told the Court decided means "an area on the slide's upper surface where reagents are added and mixed." This was confirmed by Mr. Leon in his deposition. *See* Leon Depo. p. 55:1-15 ("Q. And so that slide clip provides walls that define an area on a slide, right? A. Correct. Q. That's the area where a sample will be mounted on the slide, correct? A. Correct. Q. And that's the area where reagents will be dispensed? A. Correct. Q. That's the area where the bulk fluids will be dispensed as well? A. Correct. Q. And that's the area where the reagents will be mixed, correct? A. Correct.").

16. Element [e] of claim 1 calls for "an air mixer comprising an air jet and an air supply means positioned adjacent to a said reagent agitation zone for mixing reagents, said air mixer directing a jet of air at the reagent agitation zone thereby inducing mixing in the reagent agitation zone." The Artisan has an air mixer which "directs an oscillating air jet onto the slide at the mixing station for agitating the contents of the slide. It consists of an air nozzle and a stepper motor for moving the nozzle back and forth horizontally above the slide." Service Manual p. 16. The "air stream mixes and evenly distributes the reagents over the surface of the slide." User Guide p. 13. *See also* Leon Depo. p. 62:24-63:1 ("Q. Okay. In the Artisan the mixer uses air to mix the reagents, right? A. Correct."). I note that during his deposition, Mr. Leon referred to the nozzle mentioned in this documentation as a "plenum." *See* Leon Depo. p. 70:19-71:2. The rectangular slit and the surrounding internal boundaries that define that slit within the plenum constitute the nozzle described in element [e] and defined by the Court's claim construction.[1] When the plenum is in the home position

[1] I also note that the nozzle, or "plenum," referred to in the DakoCytomation documentation and by Mr. Leon includes other functionality besides that of a nozzle, including that of a sensor flag as well as a guide that prevents rotation of the plenum. *See* Leon Depo. p. 97:3-9.

and at the beginning and end of each mixing cycle, the nozzle and the air jet are next to, but not above or beneath the reagent agitation zone as defined by the Court. *See* Leon Depo. p. 96:25-97:2.

17. I have been asked to consider whether the Artisan's air mixer performs substantially the same function, in substantially the same way, to achieve substantially the same result, as the claimed "air mixer" of element [e]. I conclude that it does.

18. The function of the air mixer as called for in claim 1 is to mix reagents in a reagent agitation zone of a slide. According to the User Guide, the Artisan air mixer "mixes and evenly distributes the reagents over the surface of the slide." User Guide p. 13; *see also* Service Manual p. 12 ("A separate mixer station allows reagents to be mixed and uniformly spread on each slide."). I conclude that the Artisan mixer performs the same function as is described by element [e] of the claim.

19. The way the above function is performed is through mechanical agitation of the reagents caused by the transfer of kinetic energy from the air jet to the reagents. The air mixer in the Artisan works in the same way in that it "directs an oscillating air jet onto the slide at the mixing station for agitating the contents of the slide." Service Manual p. 16.

20. The result of the claimed mixing of element [e] is increased uniformity of the reagent solution and increased interaction of the reagents with the sample. The air mixer in the Artisan achieves this same result. As Mr. Leon confirmed, the mixing achieves "more of a uniform mixture when there's more than one reagent on there." *See* Leon Depo. p. 62:9-17. A further result of the mixing in the Artisan is spreading the reagent onto the sample surface, thus increasing the interaction between the reagent and the sample. *See* Leon Depo. p. 62:18-23.

21. I have been asked to consider whether as of December 2004, the air mixer device in the Artisan was known to be interchangeable with an air mixer that is positioned next to, but never above or beneath the reagent agitation zone. I conclude

that it was. The goal of mixing is to increase the uniformity of the reagent solution and to agitate the reagents relative to the sample. An engineer designing such a system in 2004 would know that this can be accomplished with a moving, vertical air jet that originates from above or with an angled air jet that originates from the side. Both air mixers transfer kinetic energy from the air jet to the reagents, achieving the above goal.

Claim 2

22. Claim 2 states "The biological reaction apparatus of claim 1, wherein said sample carousel may be arranged to allow said sample supports to be positioned in said reagent supply zone." In the Artisan, "Each slide rotates to the dispensing station, where the appropriate reagent pack positions itself above the slide." User Guide p. 13. The Artisan includes a slide carousel positioning system which "places the correct slide at one of these stations, depending on the operation required by the staining protocol: Reagent dispensing . . . " Service Manual p. 14. Mr. Leon validated this feature of the Artisan during his deposition when he confirmed that "if you wanted a particular slide to get a reagent the slide carousel would rotate so that that slide is in the reagent dispensing station." Leon Depo. p. 56 :11-15. During my observation of the Artisan, I confirmed that the sample carousel can rotate and position slide samples on supports in the "reagent supply zone" (*i.e.*, reagent dispensing station).

Claim 3

23. The preamble of claim 3 calls for "The biological reaction apparatus of claim 1, wherein the reagent carousel is rotatably mounted on a reagent carousel support." The reagent carousel of the Artisan rotates around a "reagent carousel mounting ring." Leon Depo. p. 60:8-10. This reagent carousel mounting ring is the reagent carousel support described in the preamble of claim 3.

24. The next element of claim 3 states "wherein the homing and indexing device further comprises a proximity detector and an object detectable by the proximity detector when the proximity detector and said object are in close proximity, one of said object and said proximity detector being mounted on the reagent carousel, and the other of the object and said proximity detector being mounted on the reagent carousel support in a position adjacent the path of the other." The Artisan includes a reagent carousel home sensor mounted on the stationary reagent carousel mounting ring. The Artisan also includes a reagent carousel home sensor flag mounted on the reagent carousel. This flag is detectable by the home sensor when the home sensor and the flag are in close proximity. The sensor and flag are shown in Figure 8-17 of the Service Manual:

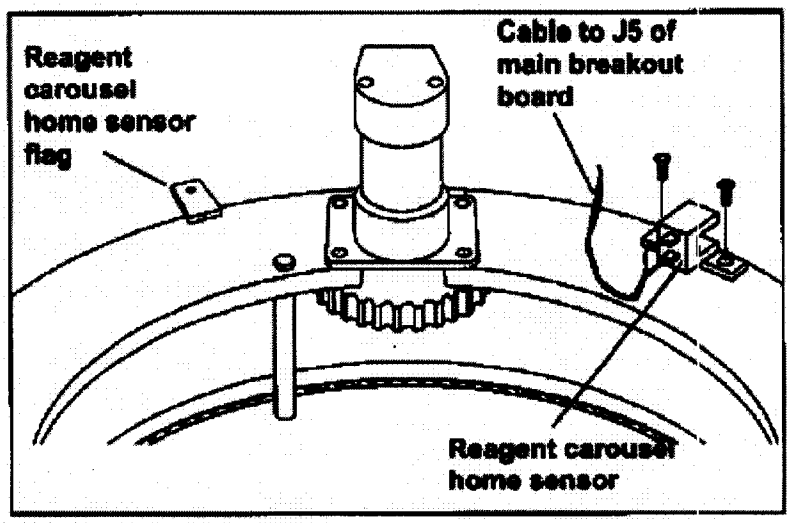


Figure 8-17. Removal of the reagent carousel home sensor

This arrangement was confirmed by Mr. Leon in his deposition. *See* Leon Depo. p. 41:12-42:12. When the reagent carousel rotates such that the home sensor flag is detected by the home sensor, the Artisan determines the home position of the reagent carousel.

Claim 45

25. The preamble and elements [a], [b] and [e] of claim 45 are identical to the preamble and elements [a], [b] and [e] of claim 1. As described above, the Artisan includes all aspects of these elements.

26. Element [c] of claim 45 calls for "a motor engaging the reagent carousel and operatively coupled to said homing and indexing device, for rotating the reagent carousel and positioning a preselected reagent container support in a reagent supply zone, wherein said reagent supply zone is oriented so that reagent in a container in said preselected reagent container support is dispensable to a slide sample and wherein each of the reagent container supports is arranged to accommodate a reagent container such that it is positioned above a slide sample when in the reagent supply zone whereby the reagent is dispensable from a lower end of said container onto the slide sample." This element differs from element [c] of claim 1 only by the addition of the word "sample" following the word "slide." In other words, the word "slide" in claim 1 is replaced by the phrase "slide sample" in claim 45. Despite this substitution, and for the reasons stated above in connection with element [c] of claim 1, the Artisan includes all the aspects of element [c] of claim 45.

27. Element [d] of claim 45 calls for "a carousel arranged beneath said reagent carousel for cooperation therewith, and having a plurality of slide supports with each slide support engaging a slide including a sample, said slide having a substantially planar support surface, said slide having a reagent agitation zone for adding and mixing reagents thereto located on the slide's upper surface." This element differs from element [d] of claim 1 only by the deletion of the word "sample" prior to the word "carousel" and the addition of the phrase "including a sample, said slide" following the phrase "engaging the slide." Despite these changes, and for the reasons stated above in connection with element [d] of claim 1, the Artisan includes all the aspects of element

[d] of claim 45. Furthermore, the above discussion of whether the Artisan's air mixer performs substantially the same function, in substantially the same way, to achieve substantially the same result, as the claimed "air mixer" of element [e] applies equally to claims 1 and 45.

Dated: 1-31-06

Andre Sharon, Ph.D.

Exhibit D

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VENTANA MEDICAL SYSTEMS, INC., Plaintiff, v. DAKOCYTOMATION CALIFORNIA INC., Defendant.	C.A. No. 04-1522-GMS

EXPERT REPORT OF DR. ARI GLEZER

I. INTRODUCTION

My name is Dr. Ari Glezer. I have been engaged as an expert by DakoCytomation California Inc. (“Dako”) to analyze and provide opinions concerning whether the Artisan® staining system infringes the certain claims of U.S. Pat. No. 6,827,901 B2 entitled, "Automated Biological Reaction Apparatus" ("the '901 patent") asserted by Ventana Medical Systems, Inc. ("Ventana") in this matter (C.A No. 04-1522-GMS) and to comment on the expert report of Ventana’s expert, Dr. Andre Sharon. This report contains my conclusions and a summary of my analysis. The report is structured as follows:

- A summary of my conclusions.
- An overview of my qualifications to render an expert opinion.
- A list of resources available to me that help form the basis of my opinions.
- The legal principles applicable to this analysis.
- An overview of the subject covered by the patent.
- My opinion on the validity of the relevant claims.

II. SUMMARY OF CONCLUSIONS

Based on my review of the matters listed below, my understanding of the Court's claim construction and my understanding of the prevailing legal principles, I conclude that Dr. Andre Sharon's expert report failed to establish that the Artisan® infringes claims 1, 2, 3, and 45 of the '901 patent and that the Artisan® does not infringe claims 1, 2, 3, or 45 of the '901 patent, literally or by equivalence.

III. BACKGROUND AND QUALIFICATIONS

I have over 30 years of engineering design and research experience in the field of mechanical engineering with particular focus on manipulation and control of shear flows. I am currently the George W. Woodruff Chair in Thermal Systems and a Professor of Fluid Mechanics at the School of Mechanical Engineering of the Georgia Institute of Technology. My research focuses on macro- and microscale fluid mechanics and heat transfer processes, flow control, actuators and sensors, and diagnostics. An important aspect of my work has been the development of novel actuator technologies that have included electromechanical-, fluidic- and chemical-based actuators.

I earned my B.S. degree in Mechanical Engineering from Tel Aviv University (Tel Aviv, Israel) in 1974 and my M.S. and Ph.D. degrees in Aeronautics from the California Institute of Technology (Pasadena, CA) in 1975 and 1981, respectively.

After receiving my doctorate from the California Institute of Technology, I worked as a senior research engineer at the Aircraft Division of Northrop Corporation. I joined the faculty of the University of Arizona as an Assistant Professor in 1984 and was promoted to Associate Professor. I was hired as an Associate Professor at the Georgia Institute of Technology in 1992.

I have published over 120 archival and conference articles and I am listed as inventor on 19 patents in the field of mechanical engineering, including areas of shear flow and actuator technologies.

I have been the recipient of numerous awards, including the Georgia Institute of Technology College of Engineering Research Award and the American Society of Mechanical Engineers Lewis F. Moody Award.

I have given lectures at various engineering meetings, including a keynote lecture at the Fifth Microgravity Fluid Physics Conference and a keynote lecture at the International Symposium on Turbulence and Shear Flow Phenomena.

I have supervised many masters and doctoral candidates in their research and preparation of theses. I have taught and developed undergraduate and graduate-level courses at the University of Arizona and at the Georgia Institute of Technology.

Additional details on my background and experience appear in my curriculum vitae, which is attached as exhibit A.

I have testified as an expert witness for the law firm of King and Spalding by deposition within the last four years on behalf of Coca-Cola Corporation v. PepsiCo.

I am being compensated at $350 per hour for consulting work.

IV. INFORMATION CONSIDERED

In forming my opinions for this report, I have considered some or all of the following documents:

- United States Patent No. 6,827,901;
- The file history for United States Patent No. 6,827,901;
- Court order construing the terms of the ‘901 patent;
- Expert report of Dr. Andre Sharon;
- Ventana’s preliminary infringement contentions;
- Dako’s preliminary non-infringement contentions;
- In-scale technical drawings of the air mixer and slide assembly;
- Samples of the slide clip assembly and air mixer assembly; and
- A personal inspection of an Artisan® instrument

V. MY UNDERSTANDING OF THE APPLICABLE LEGAL PRINCIPLES

A. Infringement

I understand that determining infringement is a two step process. First, the claims are interpreted or "construed" by the Court, and second, the claims, as construed, are compared to the accused product.

I understand that there are two types of patent infringement: "literal infringement" and infringement under the "doctrine of equivalents." For a product to literally infringe a claim, each and every limitation in the claim must be found in the product. If a single limitation of a claim is not found in a product, then the product does not infringe the claim.

If a product does not literally infringe (i.e., an element of the claim is not found in the product), then the product might still infringe under the "doctrine of equivalents," if an "equivalent" feature is present. I am informed that for a product feature to be "equivalent" to a claim element under the doctrine of equivalents, the feature must perform substantially the same function, in substantially the same way, to achieve substantially the same result as the claim element. I am also informed that "equivalence" is determined on an element-by-element basis, rather than by comparing the product as a whole to the claim as a whole. In other words, a product cannot infringe a claim under the doctrine of equivalents if a claim element is entirely lacking.

I further understand that dependent claims include all the limitations of each claim from which they depend. Therefore, if an independent claim is not infringed, then any claims that depend therefrom are also not infringed.

B. Level of ordinary skill in the art

The subject matter of the ‘901 patent is the automation of biological protocols that were traditionally done manually. Since this field of art is at the intersection of two disciplines, biology and mechanical engineering, two types of persons have ordinary skill in the art of biological protocols automation. From the mechanical engineering side, a person having

ordinary skill in the art to which the patented subject matter pertains, at the time the claimed inventions were made, is typically an engineer with a B.S. in engineering (or the equivalent) and with experience in instrument design. From the biology side, a person having ordinary skill in the art to which the patented subject matter pertains, at the time the claimed inventions were made, is a biologist with perhaps a B.S. in biology or the equivalent; who has significant experience with the essence of the biological protocol that was being automated; and who has a general understanding and experience with automation in a laboratory setting. For example, if the biological protocol was immunostaining, a person having ordinary skill in the art would have a through understanding of immunostaining protocols and have significant experience using automated machines in the laboratory.

VI. THE '901 PATENT

The invention of the '901 patent is an automated biological reaction apparatus. Many experiments or protocols in biology involve serial application of different liquids or reagents to produce a biological or biochemical reaction. Carrying out these protocols is labor intensive. The invention of the '901 patent is a machine that automates these routine procedures to provide for "more rapid, reliable and more reproducible results," all with less labor. (Col. 2, lines 36-45).

Most biological reactions require certain basic steps. If only liquids are involved in the reaction, these steps are usually: adding reagents to the reaction, mixing the reagents in the reaction, incubating the reaction for a certain amount of time usually at a specified temperature, and then assaying the results. If the protocol requires that the liquids be in contact with a solid sample, then a rinsing step might be involved before another reagent is added. An example of such a protocol is the technique of immunohistochemistry, which is used as an example in the '901 patent of a reaction that can be automated. (Col. 6, lines 34-37).

I am informed that only claims 1, 2, 3 and 45 are asserted in the present litigation. I will therefore limit my analysis where possible to claims 1, 2, 3 and 45. There are many elements or limitations in claims 1, 2, 3 and 45. I will concentrate my analysis on what I see as the two

limitations that are not satisfied by the Artisan® staining machine. Claims 1, 2, 3 and 45 are reproduced below as follows with the two limitations mentioned above highlighted:

1. A biological reaction apparatus for dispensing a selected reagent to a slide containing a sample, said biological reaction apparatus comprising:

a reagent carousel having a ***plurality of reagent container supports*** thereon;

a homing and indexing device, operatively coupled to the reagent carousel, for identifying the position of each reagent container support with reference to a home position;

a motor engaging the reagent carousel and operatively coupled to said homing and indexing device, for rotating the reagent carousel and positioning a preselected reagent container support in a reagent supply zone, wherein said reagent supply zone is oriented so that reagent in a container in said preselected reagent container support is dispensable to a slide and wherein each of the reagent container supports is arranged to accommodate a reagent container such that it is positioned above a slide when in the reagent supply zone whereby the reagent is dispensable from a lower end of said container onto the slide;

a sample carousel arranged beneath said reagent carousel for cooperation therewith, and having a plurality of slide supports with each support engaging a slide having a substantially planar support surface, said slide having a reagent agitation zone for adding and mixing reagents thereto located on the slide's upper surface; and

an air mixer comprising an air jet and an air supply means positioned adjacent to a said reagent agitation zone for mixing reagents, said air mixer directing a jet of air at the reagent agitation zone thereby inducing mixing in the reagent agitation zone.

2. The biological reaction apparatus of claim 1, wherein said sample carousel may be arranged to allow sample supports to be positioned in said reagent supply zone.

3. The biological reaction apparatus of claim 1, wherein the reagent carousel is rotatably mounted on a reagent carousel support, and

wherein the homing and indexing device further comprises a proximity detector and an object detectable by the proximity detector when the proximity detector and said object are in close proximity, one of said object and said proximity detector being mounted on the reagent carousel, and the other of

the object and said proximity detector being mounted on the reagent carousel support in a position adjacent the path of the other.

45. A biological reaction apparatus for dispensing a selected reagent to a slide containing a sample, said biological reaction apparatus comprising:

a reagent carousel having a ***plurality of reagent container supports*** thereon;

a homing and indexing device, operatively coupled to the reagent carousel, for identifying the position of each reagent container support with reference to a home position;

a motor engaging the reagent carousel and operatively coupled to said homing and indexing device, for rotating the reagent carousel and positioning a preselected reagent container support in a reagent supply zone, wherein said reagent supply zone is oriented so that reagent in a container in said preselected reagent container support is dispensable to a slide sample and wherein each of the reagent container supports is arranged to accommodate a reagent container such that it is positioned above a slide sample when in the reagent supply zone whereby the reagent is dispensable from a lower end of said container onto the slide sample;

a carousel arranged beneath said reagent carousel for cooperation therewith, and having a plurality of slide supports with each slide support engaging a slide including a sample, said slide having a substantially planar support surface, said slide having a reagent agitation zone for adding and mixing reagents thereto located on the slide's upper surface; and

an air mixer comprising an air jet and an air supply means positioned adjacent to said reagent agitation zone for mixing reagents, said air mixer directing a jet of air at the reagent agitation zone thereby inducing mixing in the reagent agitation zone.

I note that claims 1 and 45 are identical with respect to the two limitations where I plan to concentrate my analysis, therefore my analysis will apply equally to both claims 1 and 45.

VII. CLAIM CONSTRUCTION

I understand that in analyzing whether a claim is valid, one must consider how the language has been interpreted or "construed" by the Court. The claims, as construed, are then compared to the prior art. I have been informed that the Court has issued a claim construction ruling. According to the ruling,

- The term “reagent agitation zone” is construed as “an area on the slide's upper surface where reagents are added and mixed.”
- The term “air mixer” is construed as “the device, including the air jet and the air supply means, that is positioned adjacent to the reagent agitation zone for mixing reagents.”
- The term “air jet” is construed as “a stream of air.”
- The term “air supply means” is construed as “a device for supplying air, comprising the nozzle.”
- The term “adjacent” is construed as “next to, but not above or beneath.”

I understand that terms that have not been construed by the court the parties have agreed should be given their ordinary meaning to one skilled in the art.

an air mixer comprising an air jet and an air supply means positioned adjacent to said reagent agitation zone for mixing reagents, said air mixer directing a jet of air at the reagent agitation zone thereby inducing mixing in the reagent agitation zone

The Court has construed several terms in the above limitation. According to the Court’s construction, I understand the above limitation to require several features before an accused product can be found infringing. First, the accused product must possess a reagent agitation zone which is an area on the slide’s upper surface where reagents are added and mixed. Second, the air mixer of the accused product must contain at least a stream of air and a nozzle. Third, the air mixer of the accused product must be positioned next to, but not above or beneath, an area on the slide’s upper surface where reagents are added and mixed. Fourth, the air mixer of the accused product must direct a stream of air at the reagent agitation zone. And finally the air mixer of the accused product must induce mixing of reagents in the reagent agitation zone.

plurality of reagent container supports

The Court has not construed any terms in the above limitation and I will therefore read this limitation as one of ordinary skill in the art would read the limitations. As one of at least

ordinary skill in the art, I would interpret the word "support" as supporting the weight of. So a reagent container support is something that holds up or props up or serves as a foundation for the weight on a reagent container. I interpret the term "plurality" to mean more than one. Accordingly, the "plurality of reagent container supports" limitation requires that the accused device contain more than one props or foundations to support the weight of the reagent containers. This interpretation is in accord with the specification of the '901 patent. The '901 patent describes multiple holes in the reagent carousel with each of these holes able to support the weight of one reagent container.

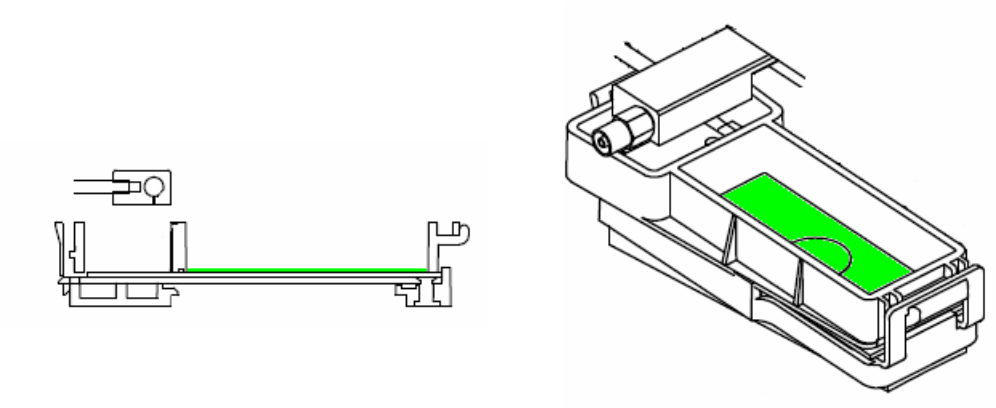
VIII. INFRINGEMENT ANALYSIS

an air mixer comprising an air jet and an air supply means positioned adjacent to said reagent agitation zone for mixing reagents, said air mixer directing a jet of air at the reagent agitation zone thereby inducing mixing in the reagent agitation zone

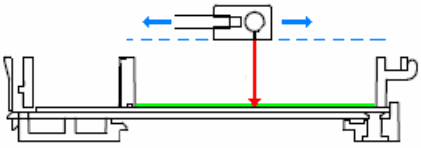
In my opinion, there are three independent bases for why the Artisan® does not satisfy the above limitation of the '901 patent, either literally or under the doctrine of equivalents.

The air mixer in the Artisan® employs a rectangular air jet that slides back and forth above the surface of a slide. It directs a thin jet of air down at a walled tub of reagents that rests on the sample slide. The action of this jet causes free surface waves and sloshing motion in the tub, which distribute and mix the reagents. A cross section of the slide and tub is shown below.

The reagent agitation zone was construed by the Court to mean an area on the slide's upper surface where reagents are added and mixed. During the operation of the Artisan® machine, there is only one area on the slide's upper surface where reagents are added and mixed. This area corresponds to an area bounded by the inner walls of a slide clip that is fastened onto the slide and retains reagents on the slide's upper surface. The area corresponding to the reagent agitation zone is shown below highlighted in green.



The Artisan® air mixer is pictured below. Air flows out of a narrow slit opening at the bottom of a plenum. This air (shaded in red) is directed straight down toward the reagent agitation zone. As the plenum sweeps back and forth over the slide, the air jet impinges on the free surface of the reagents creating waves and sloshing and, thereby, spreading and mixing them.



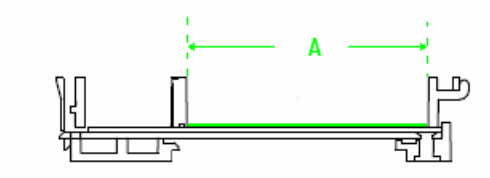
Throughout this motion, the air mixer remains above the reagent agitation zone. Therefore, it is my opinion that the Artisan® does not satisfy the "adjacent" limitation, the limitation that requires the air mixer of the accused product to be positioned next to, but not above or beneath, an area on the slide's upper surface where reagents are added and mixed.

The Artisan® Does Not Infringe the '901 Patent Because When the Artisan® Air Mixer is Directing a Jet of Air at the Reagent Agitation Zone, the Air Mixer is Positioned Above the Reagent Agitation Zone

For infringement to occur, the claim limitations require that the air mixer of the accused product be positioned next to, but not above, the reagent agitation zone ***and*** that the said air mixer direct a stream of air at the reagent agitation zone. In my opinion the Artisan® does not

infringe the ‘901 patent because at no time during the operation of the Artisan® does the Artisan® satisfy both the above limitations.

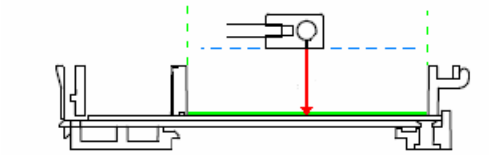
For convenience of analysis, I will divide into two regions the places where the Artisan® air mixer can be found. The region I designate as Zone A is illustrated below.



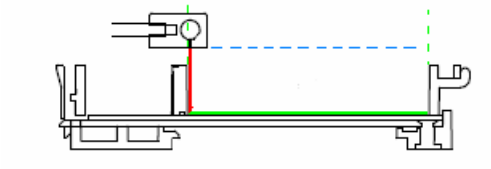
At all times during the operation of the Artisan®, the nozzle of the Artisan® plenum can only be in one of two places: within Zone A and outside of Zone A. I will address each zone in turn and show that when the nozzle of the plenum is within or outside Zone A, the Artisan® does not satisfy the limitations of the ‘901 patent.

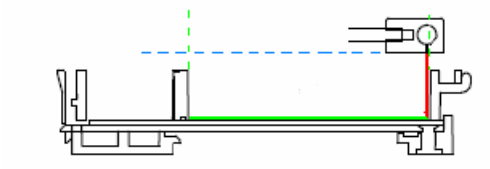
Inside Zone A

I first address the situation when the plenum and nozzle are inside Zone A which is illustrated below.



The nozzle is able to move horizontally along the dashed blue line. The two boundary situations occur when the nozzle is just barely within Zone A are illustrated below.





In all the above configurations, when the nozzle of the plenum is within zone A, the air mixer, the nozzle, and the air stream are all clearly above the reagent agitation zone. Accordingly, when the nozzle is within Zone A, the Artisan® does not satisfy the "adjacent" limitation as construed by the Court and does not literally infringe any of the '901 patent claims.

I have read Dr. Andre Sharon expert report concerning the above matter and as far as I can discern, Dr. Sharon apparently agrees with my assessment that when the nozzle of the plenum is within Zone A, the air mixer is above the reagent agitation zone. And therefore, Dr. Sharon appears to agree that the within Zone A, the Artisan® air mixer does not literally infringe the claims of the '901 patent.

Also, when the nozzle is within Zone A, the Artisan® does not infringe under the doctrine of equivalents. I have been informed that Ventana cannot argue that an air mixer positioned above the reagent agitation zone is equivalent to an air mixer positioned not above the reagent agitation zone because of the principle of claim vitiation – i.e. if Ventana is allowed to argue that an air mixer positioned above is equivalent to an air mixer positioned not above, that would effectively eliminate the "not above" limitation from the claim language. I also believe that to argue that something "above" is equivalent to something "not above" is self contradictory.

Further, I believe that an air mixer positioned above the reagent agitation zone is not an equivalent of an air mixer positioned next to, but not above or beneath, the reagent agitation zone under the previously mentioned substantially same function, way, result test. The primary functions of the Artisan® air mixer is two-fold: first to evenly distribute the reagents across the slide's and sample's upper surface and the second is to mix reagents. In this context, note that the primary function of the air mixer disclosed in the '901 patent is to mix reagents. The Ventana jet is not designed or intended to spread reagents over the surface of the slide but to mix them under the oil coating. These two functions are not substantially the same.

The method or way the two air mixers carry out the mixing function is also substantially different. The Artisan® air mixer employs an air jet to induce waves and sloshing motion on the surface of the liquid in the container that is formed by the clip. The disclosed invention employs

air jets positioned next to, but not above, the slide to create a vortex within a reagent puddle that is covered by an oil film. These two methods of mixing are not substantially the same.

I have read the portion of Dr. Andre Sharon's expert report where he opines as to whether the Artisan® air mixer performs mixing in the same way as claimed in the '901 patent. Dr. Sharon believes that the way mixing is performed in the disclosed invention is through "the transfer of kinetic energy from the air jet to the reagents." Sharon Rpt. at ¶ 19. This is simply too broad because every conceivable way of mixing liquids using air jet would require transfer of kinetic energy from the air to the reagent. As mentioned above, it is my understanding that the Ventana air jet flows along the surface of the oil film and through shear induces motion in the film. This motion results in circulatory (vertical) flow within the reagent layer underneath which ultimately leads to mixing of the reagent.

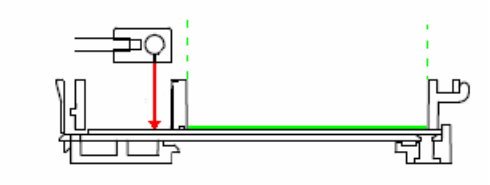
For these reasons, the Artisan® does not infringe any of the '901 patent claims under the doctrine of equivalents.

Outside Zone A

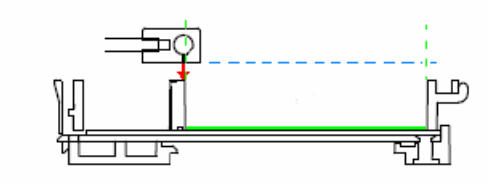
Now I will address the situation when the nozzle of the plenum is situated outside Zone A. This occurs when the plenum moves horizontal past either the left or right boundary of Zone A. In his expert report, Dr. Sharon argued that "[w]hen the plenum is in the home position and at the beginning and end of each mixing cycle, the nozzle and the air jet are next to, but not above or beneath the reagent agitation zone as defined by the Court." Sharon Rpt. at ¶ 16. In short, Dr. Sharon argues that when the plenum is outside Zone A, the nozzle and the air jet are next to, but not above or beneath the reagent agitation zone. Even if I accept Dr. Sharon's argument that when the plenum is outside Zone A, the nozzle and the air jet are next to, but not above or beneath the reagent agitation zone, the Artisan® would still not infringe the '901 patent because

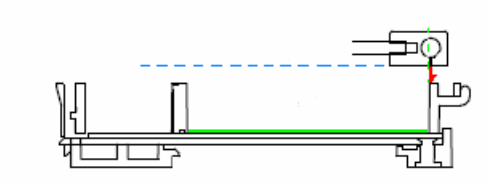
when the Artisan® air mixer is outside Zone A, the Artisan® does not satisfy the "said air mixer directing a jet of air at the reagent agitation zone" limitation.[1]

An example of plenum is in its "home position" as illustrated below. The "home position" is the furthest left that the plenum is able to move in the Artisan® machine.



The boundary situations occur when the nozzle of the plenum is just barely outside the left and right boundaries of Zone A. The two boundary situations are illustrated below.





In all these configurations, when the nozzle of the plenum is outside Zone A, the air mixer is not directing air at the reagent agitation zone. When the air mixer is in the home position, the air mixer is directing air at the bar code area. When the air mixer is in one of the two boundary situations, the air mixer is directing air at the top of the slide clip. Accordingly, when the nozzle of the plenum is outside Zone A, the Artisan® does not satisfy the "said air mixer directing a jet of air at the reagent agitation zone" limitation and therefore does not literally infringe any of the '901 patent claims.

[1] It appears that Dr. Sharon is seeking to interpret "not above" to mean "not directly above." I do not believe that this interpretation is faithful to the Court's claim construction order. If the Court changes or clarifies its claim construction, I reserve the right to supplement this expert report.

Also, when the nozzle of the plenum is outside Zone A, the Artisan® does not infringe the '901 patent under the doctrine of equivalents. The question is whether an air mixer directing a stream of air at the top of the slide clip or at the bar code area performs substantially the same function, in substantially the same way, to achieve substantially the same result as an air mixer directing a stream of air at the reagent agitation zone. In the claimed invention, the air mixer directs a stream of air at the reagent agitation zone to perform the function of mixing reagents. The Artisan® air mixer directing a stream of air at the top of slide clip performs no recognizable function. Also, an air mixer directing a stream of air at the bar code area might function to clear the bar code area of debris, but not to mix reagents. Clearing debris from the bar code area is a very different function from mixing reagents. Given that the directing air at the reagent agitation zone and directing air at the slide clip or at the bar code area does not even perform substantially the same function, the fact that the Artisan® and the claimed invention does not perform in substantially the same way to achieve substantially the same result easily follows. For these reasons, I conclude that directing a stream of air at the top of the slide clip or at the bar code area is not equivalent to directing a stream of air at the reagent agitation zone.

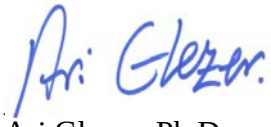
I have read Dr. Andre Sharon's expert report and I as far as I can tell, Dr. Sharon does not address whether the air mixer directs a stream of air at the reagent agitation zone when the nozzle of the plenum is outside Zone A. Dr. Sharon does opine that the air mixer directs a jet of air at the reagent agitation zone, but his statements only apply to situations where the nozzle is inside Zone A, and therefore ***above*** the reagent agitation zone. Since Dr. Sharon has failed to establish infringement when the nozzle is outside Zone A and Dr. Sharon agrees that there is no infringement inside Zone A, I conclude that Dr. Sharon's expert report does not establish infringement at any time.

X. ADDITIONAL OR AMENDED OPINIONS

I reserve the right to augment or amend my opinions in the event that I become aware of new or different information, including prior art, or in the event that the Court provides additional or different claim constructions.

XI. DECLARATION

In compliance with 28 U.S.C. § 1746, and the laws of the State of Georgia, I declare under penalty of perjury that the foregoing statements are true and correct to the best of my knowledge. Executed in Atlanta, Georgia, this 1st day of March, 2006.



Ari Glezer, Ph.D.

Dr. Ari Glezer
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Ari Glezer is a Professor of Fluid Mechanics in the George W. Woodruff School of Mechanical Engineering at Georgia Institute of Technology where he moved in 1992 from the Aerospace and Mechanical Engineering Department at the University of Arizona. Before he became a member of the faculty at the University of Arizona in 1984, Professor Glezer worked as a senior research engineer at the Aircraft Division of Northrop Corporation, and was a Research Fellow in the Faculty of Engineering at Tel Aviv University. Professor Glezer received his B.S. in Mechanical Engineering from Tel Aviv University in 1974 and his M.S. and Ph.D. in Aeronautics from the California Institute of Technology in 1975 and 1981, respectively. Professor Glezer's research interests are in the area of manipulation and control of shear flows with particular emphasis on small-scale mixing processes in non-reacting and reacting flows, diffusion convection flows in microfabricated bio-reactors, flow-controlled aerodynamic lift and drag, heat transfer processes and thermal management, and thrust vectoring and jet noise. An important aspect of this work has been the development of novel actuator technologies that have included electromechanical (e.g., piezoelectric), fluidic (synthetic jets) and chemical (combustion) based actuators. Professor Glezer's work has been supported by AFOSR, ARO, DARPA, NASA, NIH, and NSF. Industrial sponsors have included Intel, Honeywell, IBM, Sun Microsystems, CIBA-Novartis, and Hoechst Celanese. Professor Glezer has also served as an expert witness for the law firm of King and Spalding.

Professor Glezer has not had prior business and/or personal connections with the law firm of Fish & Richardson P.C. or with any of its officers or employees.

Distinctions

- American Institute of Aeronautics and Astronautics
  - Fluid Dynamics Best Paper Award, 2001
  - Associate Fellow, 2000
- University of Florida Taylor-Millsap Lecture, 2002
- Fifth Microgravity Fluid Physics Conference Keynote Lecture, 2002
- Georgia Institute of Technology College of Engineering Research Award, (with Mark Allen, 2002
- American Society of Mechanical Engineers (International Fluid Engineering Division) Lewis F. Moody Award, 2000
- International Symposium on Turbulence and Shear Flow Phenomena Keynote Lecture, 1999

Patents

- System and Method for Thermal Management by Synthetic Jet Ejector Channel Cooling Techniques, U. S. Patent 6,588,497, with Raghavendran Mahalingam, July 8, 2003
- Combustion-Driven Jet Actuator, U. S. Patent 6,554,607, with Thomas Crittenden, April 29, 2003
- Apparatus and Method for Enhancement of Aerodynamic Performance Using Pulse Excitation Control, U. S. Patent 6,612,732, with Michael Amity, July 2, 2002

- Micromachined Synthetic Jet Actuators and Applications Thereof, U. S. Patent 6,457,654, with Mark Allen, October 1, 2002
- Remotely-Operated Self-Contained Electronic Lock Security System Assembly, U. S. Patent 6,297,725, with Andrew Tischendorf, Kenneth Schultz, Gary Lehman, and Demos Andreou, October 2, 2001
- Vibration Induced Atomizers, U. S. Patent 6,247,525, with Marc Smith, June 19, 2001
- Synthetic Jet Actuators for Cooling Heated Bodies and Environments, U. S. Patent 6,123,145, with Mark G. Allen, September 26, 2000
- Miniature Reciprocating Combustion-Driven Machinery, U. S. Patent 6,109,222, August 29, 2000
- Remotely-Operated Self-Contained Electronic Lock Security System Assembly, U. S. Patent 6,107,934, with Demos Andreou, August 22, 2000
- Synthetic Jet Actuators for Mixing Applications, U. S. Patent 6,056,204, with John Wiltse, May 2, 2000
- Synthetic Jet Actuators for Modifying the Direction of Fluid Flows, U. S. Patent 5,988,522, with Barton Smith, November 23, 1999
- Modifications of Fluid Flow About Bodies and Surfaces with Synthetic Jet Actuators, U. S. Patent 5,957,413, with Barton Smith and Mark Trautman, September 28, 1999
- Remotely-Operated Self-Contained Electronic Lock Security System Assembly, U. S. Patent 5,933,086, with Andrew Tischendorf, Kenneth Schultz, Gary Lehman, and Demos Andreou, August 3, 1999
- Synthetic Jet Actuator and Applications Thereof, U. S. Patent 5,894,990, with Mark Allen, David J. Coe, Mark Trautman, and John Wiltse, April 20, 1999
- Synthetic Jet Actuator and Applications Thereof, U. S. Patent 5,758,823, with Mark Allen, Barton Smith, Mark Trautman, and John Wiltse, June 2, 1998
- Remotely-Operated Self-Contained Electronic Lock Security System Assembly, U. S. Patent 5,712,626, with Demos Andreou, January 27, 1998
- Method and Apparatus for Controlled Modification of Fluid Flow, U. S. Patent, 5,040,560, with Kris Nygaad and John Wiltse, August 20, 1991

Representative Publications

M. Oljaca, X. Gu, A. Glezer, M. Baffico, and F. Lund. 1998. Ultrasound Scattering by a Swirling Jet. *Physics of Fluids* 10(4), 886-898.

B. L. Smith and A. Glezer. 1998. The Formation and Evolution of Synthetic Jets. *Physics of Fluids* 10(2), September.

J. M. Wiltse and A. Glezer. 1998. Direct Excitation of Small-Scale Motions in Free Shear Flows. *Physics of Fluids* 10(8), 2026-2036.

R. D. James, J. W. Jacobs, and A. Glezer. 1996. A Round Turbulent Jet Produced by an Oscillating Diaphragm. *Physics of Fluids* 8, 2484-2495.

K. J. Nygaard and A. Glezer. 1994. The Effect of Phase Variations and Cross-Shear on Vortical Structures in a Plane Shear Layer. *Journal of Fluid Mechanics* 276, 21-59.

CERTIFICATE OF SERVICE

I hereby certify that on this 1st day of March 2006, true and correct copies of the foregoing **EXPERT REPORT OF DR. ARI GLEZER** were caused to be served on the attorneys of record, at the following addresses as indicated:

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